

REMARKS/ARGUMENTS

The claims have been divided into Groups as follows:

Group I: Claim(s) 1-9 and 17-26, drawn to a chemical compound of formula (I), a pharmaceutical composition, and a process for preparing a chemical compound of formula (I).

Group II: Claim(s) 10-16, drawn to use claims.

Group III: Claim(s) 27, drawn to another method for preparing a chemical compound of formula (I).

In addition election of a single disclosed specie is required.

Applicants elect, with traverse, Group I, Claims 1-9 and 17-26, for examination.

As a single disclosed specie, for examination purposes only, Applicants elect:

N-[(5-{[3-chloro-5-(trifluoromethyl)pyridine-2-yl]amino}butanoyl)hydrazine]sulfonyl}thien-2-yl)methyl]-4-fluorobenzamide

(Compound 32 on page 42 in the specification)

This specie is represented by formula I wherein

Ar<sup>1</sup> is 4-fluorophenyl-

Ar<sup>2</sup> is 2,5-thienyl-

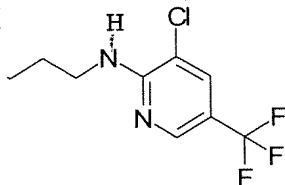
X<sup>1</sup> and X<sup>2</sup> are both O

R<sup>1</sup> is H

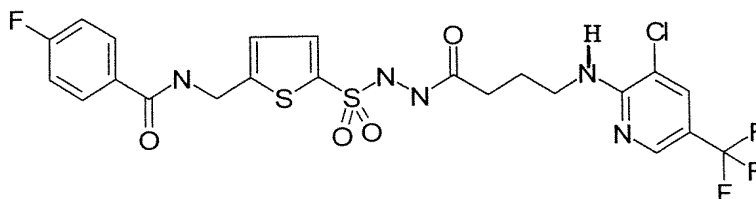
n is 1

R<sup>2</sup> = R<sup>3</sup> = H

G is



and the complete structure is



Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required (MPEP §803). The burden is on the Examiner to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP §803). Moreover, when citing lack of unity of invention in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other group specifically describing special technical features in each group (MPEP § 1893.03(d)).

The Examiner has asserted that Groups I - III do not meet the requirement for Unity of Invention for the following reasons:

- 1) the permissible combinations under Annex B Part 1(e) are lacking, and
- 2) a common structure is not present under Annex B, Part 1(f) in which the utility is attributed.

Annex B of the Administrative Instructions under the PCT at (b) Technical Relationship states:

“The expression “special technical features” is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).”

Further, at paragraph (e)

“The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of said product, and an independent claim for a use of the said product, . . .”

Furthermore MPEP §806.03 can be applied in this application:

“Where the claims of an application define the same essential characteristics of a *single* disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.”

Applicants respectfully submit that Claim 27 is a different definition of the same disclosed subject matter as in Claim 18 which is included in Group I. In addition, Claims 10-16 define use claims according to (e)(i) above. Claims 17 and 26 depend from Claims 1 and 2 respectively and therefore should not be considered for restriction.

MPEP § 1850 (B) “*Markush Practice*” states:

“When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)(1) A common structure is present, i.e., a significant structural element is shared by all the alternatives;”

Applicants respectfully submit that in the above identified application, the compounds of formula (I) do have the common property as defined on page 1, lines 7-9, in the specification and therefore meet criterion (A).

Relative to criterion (B)(1) paragraph (f)(ii) defines “significant structural element is shared by all the alternatives” as “cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, . . .” Moreover the PCT in the PCT International Search and Preliminary Examination Guidelines provide guidance in this matter through example analysis. Applicants respectfully submit that Examples 18 and 19 on pages 84 and 85 of the document are suitable references relative to analysis of formula (I). Applicants submit that the compounds of formula (I) all share the common structural features

as described by the formula and that this common structure constitutes a structurally distinctive portion sufficient to meet criterion (B)(1).

Because the compounds of formula (I) meet the criteria of (A) and (B)(1) above, Applicants submit that the claims of the above-identified application relate to a single general inventive concept under PCT Rule 13.1 and therefore unity of invention is not lacking.

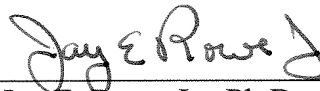
Applicants respectfully traverse the Restriction Requirement on the grounds that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the identified groups.

For the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the Restriction Requirement. Withdrawal of the Restriction Requirement is respectfully requested.

Applicants submit that the above-identified application is now in condition for examination on the merits, and early notice of such action is earnestly solicited.

Respectfully submitted,

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